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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/813,315	03/30/2004	Ramesh Babu Jayaraman	TRTC-0003	3642

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EXAMINER	
KENNEDY, SHARON E	
ART UNIT	PAPER NUMBER
1615	
MAIL DATE	DELIVERY MODE
10/02/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/813,315	JAYARAMAN ET AL.	
	Examiner	Art Unit	
	Sharon E. Kennedy	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-96 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-96 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-11, 13-40, drawn to a bioimplantable device having a therapeutic agent, classified in class 424, subclass 422.

II. Claims 41, 84, drawn to a method of inhibiting/preventing hyperplasia by contact with a prosthetic device, for example, a prosthetic graft, classified in class 623, subclass 1.42

III. Claim 42, 85-87, drawn to a method of delivery a therapeutic agent to a target location, classified in class 424, subclass 422.

IV. Claims 12, 43-83, 94-96, drawn to a vascular graft or endograft (claim 12), classified in class 623, subclass 23.64. (Note is made of the preamble problems in claims 61-66, it is assumed that applicant intended to preamble to refer to a graft and not a device.

V. Claims 88, 89, drawn to a method of forming a prosthetic graft, classified in class 623, subclass 11.11.

VI. Claim 90, drawn to a method for forming a coating of a medical device, classified in class 427, subclass 2.1.

VII. Claims 91-93, drawn to a coating applied of a medical device, classified in class 427, subclass 2.1.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the method, which requires contacting the device with a vessel, does not limit the practice of the product as claimed. The product has numerous uses, and can be a sub dermal birth control device, a post surgical ocular contact lens, etc.

Inventions II and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the product as claimed can be used in situations besides inhibiting or preventing hyperplasia in view that no drugs are claimed which would prevent hyperplasia, with the exception of claims 77 and 78. Further, the drugs which are claimed have many other applications. For example, the product can be used as an implant to deliver paclitaxel or rapamycin to a tumor site.

Inventions I, III and II, IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions have different designs and modes of operation. One is

directed to a vascular graft, one set is directed to a bioimplantable device with numerous uses including being formulated as a catheter. Applicant claims a vascular prosthesis in claim 13, however, this is not necessarily a stent and is commonly interpreted to be a long term use vascular access device (e.g. catheter). The stent (claim 10) can be an intra-urethral stent for a patient suffering from prostate problems or bladder crystals. In addition, note is made that applicant admits the polyether urethane having the modified siloxane surface is known and commercially available under the trademark Thoralou^{R}. See [0023] of the specification. The inventions cannot be related merely because they contain the same known polymer. Applicant may argue that Invention I,III encompasses Invention II, IV due to the similarity of claims 6-14 as compared to 46-52, however, claims 46-52 are improper. A vascular graft does not encompass a stent, anatomical support device, or a catheter.

Inventions IV and V are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make another and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product can be made by another process. Note that the methods of making recite two different ways of applying the therapeutic to the polymer.

Inventions VI and VII are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make another and materially different product or (2)

that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the method of making really contains no steps of forming the coating and is vague and indefinite, but this is does preclude restriction. Note is made of the various coating examples in the specification. In general, coatings can be applied numerous ways, such as dipping, spraying, sputtering, painting, etc.

Inventions I, III and VI, VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions have different designs, modes of operation, and effects. One is directed to an implantable device, which can be a drug delivery device, the other is related to a coating for a prosthetic, for example. In addition, note is made that applicant admits the polyether urethane having the modified siloxane surface is known and commercially available under the trademark Thoralou^{R}. See [0023] of the specification. The inventions cannot be related merely because they contain the same known polymer.

Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions have acquired a separate status in the art in view of their different classification, restriction for examination purposes as indicated is proper.

Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions have acquired a separate status in the art due to their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Election/Restrictions

This application contains a disclosure including claims directed to the following patentably distinct species containing the various embodiments described below:

Bioimplantable Device: If applicant chooses Group I or the method of use thereof, applicant must select one of the following uses: service in an organ, service in a tissue, service as an anatomical support, shunt, stent, stent graft, vascular prosthesis, catheter. (Note is made of the same listing from Group III, but as stated above, the examiner does not consider this to be an acceptable listing.)

Therapeutic Drug Loading: If applicant chooses Group I or the method of use thereof, applicant must also, in addition to the above selection, select one of the loading scenarios: all drug loaded on siloxane region, only some drug loaded siloxane region.

Therapeutic Drug Loading: In applicant chooses Group IV of the method of use, applicant must select one of the loading scenarios: Plurality of agents loaded on different layers, plurality of agents loaded onto the same layer.

The species are independent or distinct because claims to the different species recite the mutually exclusive characteristics of such species. In addition, these species are not obvious variants of each other based on the current record.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, no claim appears to be generic.

There is an examination and search burden for these patentably distinct species due to their mutually exclusive characteristics. The species require a different field of search (e.g., searching different classes/subclasses or electronic resources, or employing different search queries); and/or the prior art applicable to one species would not likely be applicable to another species; and/or the species are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that a reply to this requirement must include (i) an election of a species to be examined even though the requirement may be traversed (37 CFR 1.143) and **(ii) identification of the claims encompassing the elected**

species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

The election of the species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the election of species requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected species.

Should applicant traverse of the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the species unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other species.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141.

A telephone call was made to Patrick Farley on September 26, 2007 to request an oral election to the above restriction requirement, but did not result in an election being made.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharon E. Kennedy whose telephone number is 571/272-4948. The examiner can normally be reached on Monday-Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached on 571/272-8373.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Sharon E. Kennedy/
Sharon E. Kennedy
Primary Examiner
Art Unit 1615